# WEEKLY EPIDEMIOLOGICAL REPORT

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Ministry of Health


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## AEFI Surveillance : Data analysis

All Medicines are rarely cause side effects or adverse reaction. Compared to the other pharmaceuticals, vaccine adverse reactions are rare.

Vaccines associated with risk of adverse reactions; commonly for minor and rarely for serious adverse reactions. All vaccines go through the process of testing for safety during pre licensure (clinical trails). National regulatory authorities (NRA) and World Health Organization (WHO) closely review good manufacturing process (GMP) including all the pre clinical safety data before the registration and pre-qualification for each vaccine. But yet, close monitoring for adverse reactions particularly in post licensure period is important and necessary, since not all adverse reaction are identified during the clinical trials.

*Adverse reactions of vaccines are mainly*

- ☑ Vaccination reaction.
- ☑ Programme errors
- ☑ Coincidental
- ☑ Injection reaction

**Vaccine reaction:** Due to the inherent properties of vaccine there may be minor (commonly) and severe (rarely) vaccine reaction. It may be also either local or systemic reaction.

**Programme error:** Mainly due to improper handling, preparation and administration errors of vaccination. Training and supportive supervision of health care workers will minimize them.

**Coincidental:** Events that happen after immunization, but vaccine has no causative link to the event. With good awareness and an improved surveillance system, there is a strong possibility of increased number of coincidental reports. This is the challenge, particularly with severe reactions including deaths reported following vaccination. Only a proper investigation supported by good causality assessment including, clinical, laboratory, autopsy (in case of a death) and epidemiological analysis will identify the cause.

**Injection reaction:** Anxiety, pain or injection itself may cause this.

Surveillance of Adverse Events Following Immunization (AEFI) in Sri Lanka started in 1996 in a phased basis and gradually improved during past 15 years covering the entire country.

**Components of AEFI surveillance**

- ☑ Detection and reporting of AEFI
- ☑ Investigation
- ☑ Data analysis
- ☑ Corrective action
- ☑ Evaluation

This WER report is focused on analysis of reported AEFI data at different levels of programme implementation. Analysis at both district and divisional level is important and Regional Epidemiologists and MOOH are responsible for data analysis at each level.

In analyzing data MOH plays an important part as it is the first operational level of best use of surveillance data. All reports should be analyzed to identify the type of AEFI , particularly the programe errors. This is largely to

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carry out corrective action in a timely manner. Before the analysis, MOH needs to verify and reassure the data for accuracy.

First, all reported AEFI data need to be line listed and followed by tabulating by place (PHM/PHI divisions), person and time. Secondly do analysis by antigens by type of reported adverse events (high fever, abscess). Number of doses administered for each antigen is the denominator for calculating reported AEFI rates for each antigen in a given time period (by month, quarter or year). Thirdly, analysis shall expand to the AEFI rates by first or second or third dose , when the antigen is administered more than once. For this, the number of doses administered for the given antigen by first, second or third need to be used as the denominator.

Regional Epidemiologist also need to perform the same analysis for the district. Analysis by MOH area will help to identify issues and may focus corrective action.

Available background rates for each type of AEFI for a given antigen give a guide to make a decision on act to reported AEFIs. (background rates are available in National Immunization handbook, published by the Epidemiology Unit and WHO references)

Tables 1 and 2 shows how to calculate AEFI rates by different antigens, by different doses for given adverse events by country and a selected MOH area during 2010.

**Case definition & Interpretation of Data**

Before any conclusion and thereby any action it is recommended to be cautious with interpretation of data. Following is an example; High fever is a known AEFI for many antigens. However, when reporting 'High Fever', what does it mean? The case definition given for high fever in AEFI surveillance system in Sri Lanka is fever >39$^0$C. Background rates given for high fever in medical literature is varied by the different level temperature (eg; 38.5$^0$c, 39$^0$C or 40$^0$c). This shows the complexity, even for a simple case definition of fever and reporting variation.

Less attention to the 'case definition' of reported AEFI is a weak point in our surveillance system. It has been observed that during reporting of AEFI, MOH staff have given less attention into the AEFI case definitions. This has led to either over reporting or under reporting of AEFI. Therefore, comparison of reported AEFI at MOH or district level with background rates need a caution.

Training and awareness of field staff on case definitions of reportable AEFI will enhance quality of AEFI surveillance. Working cases definition for most of reportable AEFI are given in "Monthly surveillance report on Adverse Events Following Immunization" (AEFI form 2). In addition, more detailed case definitions for most of AEFIs have been developed by the Brighton Collaboration and are available at *www.brightoncolaboration.org*

**Table 1: Reported selected adverse events by antigen in Sri Lanka –2010**

| Antigen | Number of doses administered | Fever (>39$^0$C) | Fever rates /1000 doses administered | Allergic reactions | Allergic reactions rates /1000 doses administered | Abscess | Abscess rates /1000 doses administered |
|---|---|---|---|---|---|---|---|
| **DPT** | 459,892 | 734 | 734/459,892 X1000 =1.6 | 373 | 373/459,892 X1000 =0.8 | 215 | 215/459,892 X1000 =0.46 |
| **Penta** | 891,472 | 740 | 740/891,472 X1000 =0.8 | 240 | 240/891,472 X1000 =0.26 | 77 | 77/891,472 X1000 =0.08 |
| Measles | 344,235 | 54 | 54/344,235 X1000 =0.15 | 287 | 287/344,235 X1000 =0.8 | 9 | 9/344,235 X1000 =0.03 |

**Table 2: Calculating adverse events rates by antigen in a defined MOH area in a define time period**

| Antigen | Number of doses administered | Fever (>39$^0$C) | Fever rates /1000 doses administered | Abscess | Abscess rates /1000 doses administered |
|---|---|---|---|---|---|
| **Penta 1** | 1681 | 1 | 1/1681x1000 =0.59 | 1 | 1/1681x1000 = 0.59 |
| **Penta 2** | 1703 | 4 | 4/1703x1000 = 2.35 | 0 | 0/1703x1000 = 0 |
| **Penta 3** | 1637 | 2 | 2/1637x1000 = 1.22 | 0 | 0/1637x1000 = 0 |
| **Penta** | 5021 | 7 | 7/5021x1000 =1.39 | 1 | 1/5021x1000 = 0.19 |

Sources : www.epid.gov.lk, www.who.int,whqlibdoc.who.int

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## Table 1: Vaccine-preventable Diseases & AFP

02nd – 08th April 2011(14th Week)

| Disease | No. of Cases by Province | | | | | | | | | Number of cases during current week in 2011 | Number of cases during same week in 2010 | Total number of cases to date in 2011 | Total number of cases to date in 2010 | Difference between the number of cases to date in 2011 & 2010 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | W | C | S | N | E | NW | NC | U | Sab | | | | | |
| Acute Flaccid Paralysis | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 02 | 24 | 29 | - 17.2 % |
| Diphtheria | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | - |
| Measles | 00 | 02 | 02 | 00 | 00 | 00 | 00 | 00 | 00 | 04 | 01 | 32 | 30 | + 6.7 % |
| Tetanus | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 06 | 07 | 14.3 % |
| Whooping Cough | 0 | 00 | 00 | 00 | 01 | 00 | 00 | 00 | 00 | 01 | 00 | 12 | 05 | + 140.0 % |
| Tuberculosis | 124 | 02 | 13 | 20 | 04 | 16 | 00 | 10 | 02 | 191 | 117 | 2243 | 2467 | - 9.1 % |

## Table 2: Newly Introduced Notifiable Disease

02nd – 08th April 2011(14th Week)

| Disease | No. of Cases by Province | | | | | | | | | Number of cases during current week in 2011 | Number of cases during same week in 2010 | Total number of cases to date in 2011 | Total number of cases to date in 2010 | Difference between the number of cases to date in 2011 & 2010 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | W | C | S | N | E | NW | NC | U | Sab | | | | | |
| Chickenpox | 13 | 02 | 10 | 05 | 03 | 05 | 08 | 05 | 11 | 62 | 29 | 1430 | 1085 | + 31.8 % |
| Meningitis | 02 GM=1 CB=1 | 01 ML=1 | 02 GL=1 HB=1 | 00 | 00 | 05 KN=5 | 00 | 00 | 00 | 10 | 03 | 278 | 401 | - 30.6 % |
| Mumps | 04 | 05 | 04 | 02 | 00 | 07 | 01 | 02 | 02 | 27 | 01 | 568 | 217 | + 161.7 % |
| Leishmaniasis | 00 | 00 | 06 MT=6 | 00 | 00 | 02 KN=2 | 07 AP=3 PO=4 | 00 | 00 | 15 | 00 | 204 | 96 | + 112.5 % |

### Key to Table 1 & 2

**Provinces:** **W**: Western, **C**: Central, **S**: Southern, **N**: North, **E**: East, **NC**: North Central, **NW**: North Western, **U**: Uva, **Sab**: Sabaragamuwa.

**DPDHS Divisions:** **CB**: Colombo, **GM**: Gampaha, **KL**: Kalutara, **KD**: Kandy, **ML**: Matale, **NE**: Nuwara Eliya, **GL**: Galle, **HB**: Hambantota, **MT**: Matara, **JF**: Jaffna, **KN**: Killinochchi, **MN**: Mannar, **VA**: Vavuniya, **MU**: Mullaitivu, **BT**: Batticaloa, **AM**: Ampara, **TR**: Trincomalee, **KM**: Kalmunai, **KR**: Kurunegala, **PU**: Puttalam, **AP**: Anuradhapura, **PO**: Polonnaruwa, **BD**: Badulla, **MO**: Moneragala, **RP**: Ratnapura, **KG**: Kegalle.

**Data Sources:**

**Weekly Return of Communicable Diseases:** Diphtheria, Measles, Tetanus, Whooping Cough, Chickenpox, Meningitis, Mumps.

**Special Surveillance:** Acute Flaccid Paralysis.

Leishmaniasis is notifiable only after the General Circular No: 02/102/2008 issued on 23 September 2008. .

### Dengue Prevention and Control Health Messages

**You have a duty and a responsibility in preventing dengue fever. Make sure that your environment is free from water collections where the dengue mosquito could breed.**

## Table 4: Selected notifiable diseases reported by Medical Officers of Health

02nd – 08th April 2011(14th Week)

| DPDHS Division | Dengue Fever / DHF* | | Dysentery | | Encephalitis | | Enteric Fever | | Food Poisoning | | Leptospirosis | | Typhus Fever | | Viral Hepatitis | | Human Rabies | | Returns Received Timely** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | A | B | A | B | A | B | A | B | A | B | A | B | A | B | A | B | A | B | % |
| Colombo | 54 | 1207 | 1 | 67 | 0 | 2 | 3 | 56 | 1 | 7 | 9 | 125 | 0 | 4 | 0 | 15 | 0 | 1 | **54** |
| Gampaha | 25 | 427 | 2 | 36 | 0 | 6 | 0 | 17 | 0 | 8 | 15 | 234 | 0 | 11 | 3 | 28 | 0 | 2 | **47** |
| Kalutara | 11 | 193 | 1 | 48 | 0 | 2 | 1 | 24 | 2 | 10 | 5 | 78 | 0 | 0 | 0 | 3 | 0 | 0 | **25** |
| Kandy | 0 | 98 | 3 | 124 | 0 | 4 | 0 | 11 | 0 | 23 | 1 | 40 | 0 | 32 | 0 | 18 | 0 | 0 | **52** |
| Matale | 3 | 49 | 1 | 44 | 0 | 2 | 0 | 9 | 0 | 3 | 3 | 60 | 0 | 6 | 0 | 4 | 0 | 0 | **67** |
| Nuwara | 5 | 30 | 11 | 91 | 0 | 1 | 0 | 13 | 0 | 12 | 1 | 17 | 1 | 27 | 2 | 5 | 0 | 0 | **69** |
| Galle | 4 | 69 | 1 | 27 | 0 | 2 | 0 | 2 | 0 | 5 | 6 | 43 | 0 | 13 | 0 | 7 | 0 | 0 | **53** |
| Hambantota | 6 | 62 | 2 | 14 | 0 | 3 | 0 | 1 | 0 | 7 | 20 | 189 | 0 | 20 | 0 | 0 | 0 | 0 | **42** |
| Matara | 13 | 87 | 1 | 21 | 0 | 1 | 0 | 5 | 0 | 1 | 7 | 124 | 1 | 22 | 3 | 8 | 0 | 1 | **41** |
| Jaffna | 2 | 124 | 0 | 52 | 0 | 2 | 0 | 96 | 0 | 10 | 0 | 2 | 3 | 153 | 0 | 12 | 0 | 2 | **18** |
| Kilinochchi | 0 | 19 | 0 | 5 | 0 | 2 | 0 | 5 | 0 | 1 | 0 | 1 | 0 | 4 | 0 | 1 | 0 | 0 | **0** |
| Mannar | 1 | 17 | 0 | 5 | 0 | 0 | 0 | 7 | 0 | 0 | 0 | 11 | 0 | 27 | 0 | 1 | 0 | 0 | **60** |
| Vavuniya | 0 | 34 | 1 | 12 | 1 | 9 | 0 | 5 | 0 | 3 | 0 | 31 | 0 | 2 | 0 | 0 | 0 | 0 | **75** |
| Mullaitivu | 0 | 5 | 0 | 19 | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 3 | 0 | 1 | 0 | 1 | 0 | 0 | **0** |
| Batticaloa | 11 | 209 | 14 | 146 | 0 | 3 | 0 | 3 | 0 | 8 | 0 | 10 | 0 | 0 | 0 | 1 | 0 | 1 | **7** |
| Ampara | 3 | 26 | 0 | 35 | 0 | 0 | 0 | 7 | 0 | 20 | 3 | 40 | 0 | 0 | 0 | 4 | 0 | 0 | **0** |
| Trincomalee | 1 | 50 | 4 | 170 | 0 | 0 | 0 | 1 | 0 | 5 | 2 | 51 | 0 | 1 | 0 | 3 | 0 | 0 | **9** |
| Kurunegala | 12 | 162 | 6 | 88 | 0 | 5 | 2 | 40 | 2 | 26 | 24 | 1023 | 4 | 36 | 0 | 12 | 0 | 0 | **39** |
| Puttalam | 3 | 192 | 1 | 62 | 0 | 0 | 0 | 6 | 0 | 1 | 5 | 53 | 0 | 6 | 0 | 2 | 0 | 1 | **11** |
| Anuradhapu | 5 | 59 | 0 | 35 | 0 | 1 | 0 | 2 | 0 | 8 | 5 | 177 | 1 | 12 | 0 | 4 | 0 | 0 | **26** |
| Polonnaruw | 3 | 78 | 0 | 19 | 0 | 1 | 0 | 4 | 0 | 8 | 4 | 51 | 1 | 1 | 0 | 4 | 0 | 0 | **14** |
| Badulla | 3 | 63 | 5 | 44 | 0 | 3 | 1 | 18 | 0 | 3 | 2 | 22 | 1 | 10 | 0 | 16 | 0 | 0 | **27** |
| Monaragala | 7 | 67 | 0 | 21 | 0 | 1 | 0 | 13 | 0 | 4 | 24 | 79 | 3 | 30 | 3 | 26 | 0 | 0 | **27** |
| Ratnapura | 6 | 142 | 6 | 143 | 0 | 3 | 0 | 11 | 0 | 5 | 2 | 136 | 0 | 16 | 0 | 17 | 0 | 0 | **0** |
| Kegalle | 6 | 80 | 0 | 33 | 1 | 7 | 0 | 20 | 1 | 8 | 3 | 102 | 0 | 8 | 2 | 28 | 0 | 0 | **9** |
| Kalmunai | 0 | 10 | 10 | 129 | 0 | 0 | 0 | 2 | 0 | 3 | 0 | 3 | 0 | 2 | 1 | 2 | 0 | 0 | **23** |
| **SRI LANKA** | **184** | **3559** | **70** | **1490** | **02** | **61** | **07** | **379** | **06** | **189** | **141** | **2705** | **15** | **444** | **14** | **222** | **00** | **08** | **33** |

**Source: Weekly Returns of Communicable Diseases WRCD).**
***Dengue Fever / DHF** refers to Dengue Fever / Dengue Haemorrhagic Fever.
****Timely** refers to returns received on or before 08th April, 2011 Total number of reporting units =320. Number of reporting units data provided for the current week: 105
**A** = Cases reported during the current week. **B** = Cumulative cases for the year.

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Comments and contributions for publication in the WER Sri Lanka are welcome. However, the editor reserves the right to accept or reject items for publication. All correspondence should be mailed to The Editor, WER Sri Lanka, Epidemiological Unit, P.O. Box 1567, Colombo or sent by E-mail to **chepid@sltnet.lk.**

**ON STATE SERVICE**

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